Arizona Health-e Connection

Privacy and Security Solutions for Interoperable Health Information Exchange

Interim Implementation Planning Report

Subcontract No.
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RTI INTERNATIONAL

PRIVACY AND SECURITY SOLUTIONS FOR INTEROPERABLE HEALTH INFORMATION EXCHANGE

State Interim Implementation Planning Report

I. Background

Purpose and scope of this report

The objective of the Interim Implementation Planning Report is to present the implementation plans generated by the Arizona Health Privacy Project (AHPP) in response to the solutions identified by the Solutions and Legal working groups. This report describes the process used by the project team to organize the Implementation Planning Working Group (IPWG) and the methods used by the group to develop implementation plans to enhance the security and privacy of health information exchanged within the state of Arizona.

The Solutions Working Group (SWG) generated a number of solutions to address the variations identified in business practices related to the exchange of health information within the state. The Legal Working Group (LWG) also generated a series of solutions to address barriers to e-health data exchange in state statues and regulations. While all the solutions generated by the SWG and LWG have the potential to improve practices related to health information exchange, the IPWG decided to prioritize among the solutions and, in some cases, combine solutions together under the umbrella of one specific project. Thus, the IPWG has defined six specific projects that will be discussed in detail in this report.

Report limitations

Every effort was made by the project team to ensure that all stakeholders from the healthcare industry as well as consumer groups were invited to participate in the IPWG. The final working group had representatives from hospitals, physician offices, laboratories, pharmacies, long term care providers, payers, public health officials and consumers. In order to ensure that all stakeholders are educated about the implementation plans generated through this process, the project team intends to post the Interim Implementations Planning Report on the project website and notify all stakeholders about the availability of the report. All feedback received from responding stakeholders will be incorporated into the final version of the report

Key Assumptions

The Arizona Health-e Connection Roadmap has led to the institution of a state non-profit e-health organization—called Arizona Health-e Connection—that, once fully funded and staffed, will lead projects related to health information technology and HIE across the state. The non-profit entity is also expected to be responsible for the security and privacy related projects recommended in this report.

II. Summary of Interim Analysis of Solutions Report

The solutions generated by the SWG fell into nine categories, as follows (see appendix D):

- Developing a regional health information exchange
- Solutions for authorization and authentication problems
- Solutions for secure information transmission or exchange
- Solutions to prevent unauthorized modifications
- Solutions for current paper-based systems, primarily focused on information exchange by fax
- Enhancing patient's role in controlling their personal health information
- Other solutions
- Solutions affecting state law/regulations
- Solutions affecting federal law/regulations

The table below illustrates how the nine categories of solutions map to the implementation plans identified by the IPWG.

Solution categories identified in the Interim Analysis of Solutions Report	Implementation Plans
▪ Developing a regional health information exchange ▪ Solutions for authorization and authentication problems	#1. Research specific technology and process solutions for a state-level master provider index to serve as a clearinghouse for all RHIOs in the state and the sharing of provider information and control of access.
▪ Developing a regional health information exchange ▪ Solutions for authorization and authentication problems ▪ Solutions for secure information transmission or exchange ▪ Solutions to prevent unauthorized modifications	#2. Research on specific technology and process solutions for authentication, authorization, access and audit.
▪ Enhancing patient's role in controlling their personal health information	#4. Education and outreach program.
▪ Developing a regional health information exchange ▪ Solutions for authorization and authentication problems ▪ Other solutions	#5. Form a group to investigate state specific data element standards issues and oversee implementation of national level standards for medical records.
▪ Solutions affecting state law/regulations ▪ Solutions affecting federal law/regulations	#6. Plans for amendment of statutes and regulations to facilitate e-health data exchange.

All the solution categories with the exception of *solutions for current paper-based systems* and two solutions within the *other solutions* category are represented in the implementation plan. Once sophisticated technology solutions are implemented for health information

exchange, it is expected that fax will no longer be as important for information sharing between entities in the health sector. Solutions that fell into the category of *other solutions* included developing interstate memoranda of understanding and exploring the use of government resources to develop the technology infrastructure for health information exchange. It is expected that these solutions will be addressed in the future as the state progresses towards developing and adopting common technologies and standards for sharing health information.

None of the solutions generated by the SWG for Arizona have been implemented within the state as yet. However, progress is being made towards the development of a state-level master provider index. The management team of this specific project is currently in the process of identifying consultants who can assist in the process of designing and implementing a master provider index. Additionally, a one-day education event is being planned for the 20th of March, 2007 as a first step towards educating stakeholders and consumers about advances being made in the state in the HIT/HIE area.

III. Review of State Implementation Planning Process

Organization of the State Implementation Planning Workgroup

The Implementation Planning Working Group (IPWG) is charged with reviewing the interim analysis of solutions, as well as the findings of the Legal Working Group (LWG) and proposing preliminary implementation plans for those solutions. The project team membership includes representation from the Arizona Government Information Technology Agency, ASU Center for Advancing Business through Technology (CABIT) and the law firm of Coppersmith Gordon Schermer & Brockelman PLC.[1] The IPWG is facilitated by Raghu Santanam from ASU CABIT and chaired by Mike Stearns, Scottsdale Healthcare.

The membership of the IPWG consists of the Project Team and representation from hospitals, physician offices, providers, laboratories, pharmacies, long term care providers, payers, public health officials and consumers (see appendix L). Once we complete the Interim Implementation Plan, we will publish this to a broader group of stakeholders to solicit feedback. The feedback will be incorporated into the final Interim Implementation Plan.

Process used to formulate, develop and assess the feasibility of the implementation plans.

The process used by the AHPP to formulate, develop and assess the feasibility of the implementations plans was to hold two IPWG meetings, as well as assign "homework" to the participants between those meetings. Using the solutions identified by the SWG, the project team determined the proposed solutions for project implementation to be discussed during the IPWG meetings.

The purpose of the first IPWG meeting, held on December 15, 2006, was to document practical approaches and actionable steps for implementing solutions identified in the Interim Analysis of Solutions Report (see appendix A). We also had a presentation by the Carl T. Hayden VA Hospital to present their internal system for sharing health information as it related to authentication, authorization and access (see appendix B & C). This provided a background for the IPWG to begin discussing possible implementation plans for Arizona Health-e Connection. The IPWG then divided into groups, focusing on the following areas:

[1] Former name: Coppersmith Gordon Schermer Owens & Nelson PLC.

- Facilitating implementation of Regional health information exchanges
- Provider Identification
- Authentication
- Authorization and Access
- Standards for exchanging patient information records

The groups were asked to focus on identifying projects for implementation and to discuss the following topics as they relate to the solutions above:

- Project Assumptions
- Project Importance
- Ease of Implementation
- Project Timeline

At the end of the meeting each group was asked to present their findings. It was interesting to note that both groups had the same general comments and recommendations.

After the meeting, we sent the IPWG members a homework packet to work on to further identify the four areas noted above as well as the following information (see appendix E & F):

- Planning assumptions and decisions
- Project ownership and responsibilities
- Project scope
- Project tasks
- Project timeline and milestones
- Means for tracking, measuring and reporting progress
- Impact assessment on stakeholders
- Feasibility assessment
- Possible barriers to implementation

We received responses back from five of the IPWG members which have been incorporated into this report.

The second meeting of the IPWG was on January 17, 2007 (see appendix G). At this meeting, we had an update presented about the Health-e Connection Roadmap in Arizona. The Governance, HIE and Rural Grant teams presented their findings. The purpose of this was to let the IPWG understand the other initiatives being carried forward in the state regarding sharing of health information. The IPWG then conducted a brainstorming session to focus on completing the project planning for the solutions identified in the first IPWG meeting. The projects the IPWG focused on were:

- State repository for disseminating best practices and technology solutions as they relate to security and privacy information sharing
- Design and implementation of an education program to enhance awareness of privacy and security business practices and solutions
- State – level master provider index using privacy and security solutions
- Research specific technology and process solutions for authentication, authorization, access and audit
- State level data element standards as they relate to HIPAA guidelines

The Legal Working Group (LWG) also convened during the January 17, 2007 meeting. The discussion centered on assigning individuals to chair topic areas to evaluate and draft potential statutory or regulatory amendments to remove barriers to e-health data exchange. The following statutes and regulations will be reviewed by the subgroups:

- Genetic testing statutes
- Communicable disease information statutes and regulations
- Mental health information statute
- AHCCCS member information regulations
- Adult Day Health Care Facility regulations
- Immunization information
- Immunity for participants in e-health data exchange
- Enforcement statute with penalties for participants who do not follow the access rules for the exchange, as well as unauthorized individuals that have not been granted access
- Medical record subpoena statute
- "Safe harbors" for security and privacy practices

Kristen Rosati, Chair of the LWG, has sent a follow up memorandum to the LWG assigning chairs to the majority of these subgroups and requesting each chair to provide an outline of the suggested statutory or regulatory provisions by February 5th (see appendix K).

IV. State-level Implementation Plans

Statewide strategy and coordination (see appendix H, I, J)

The Interim Implementation Planning Report has identified several implementation plans that encompass the solutions identified in the Interim Solutions Report. All of these implementation plans will be presented to the Arizona Health-e Connection Board of Directors for consideration with strong recommendations from the IPWG. It is expected that Arizona Health-e Connection will be responsible for funding and overseeing the implementation of the solutions generated through the AHPP project.

Implementation plans for identified solutions

The implementation plans identified by the IPWG are as follows:

I. Research specific technology and process solutions for a state-level master provider index to serve as a clearinghouse for all RHIOs in the state and the sharing of provider information and control of access**.**
II. Research on specific technology and process solutions for authentication, authorization, access and audit.
III. Create a state repository for disseminating best practices and technology solutions as they relate to security and privacy.
IV. Education and outreach program.
V. Form a group to investigate state specific data element standards issues and oversee implementation of national level standards for medical records.
VI. Plans for amendment of statutes and regulations that pose barriers to e-health data exchange.

Each of these implementation plans will be discussed in greater detail in the section below.

I. Research specific technology and process Solutions for a state-level master provider index to serve as a clearinghouse for all RHIOs in the state and the sharing of provider information and access.

The IPWG group combined several different solutions identified in the interim analysis of solutions report under this project. Examples of solutions that were considered relevant here include:

• Authorize participating entities to access the provider directory handled by the exchange. Models for such an exchange include the Centralized, Federated and the Hybrid types.
• Create clearinghouse agency to authenticate participants in the health information exchange network.
• Develop clear role-based authorization standards for all entities in the network.
• Create a centralized provider directory within the state.
• Study biometrics for authentication of individuals involved in health information exchange.
• Explore the viability of authentication tools currently available, such as card swipe access to hospitals where information can be tracked on the card itself.
• Establish provider identifier–number generated for each individual within an organization to uniquely identify individuals in the health information exchange using algorithms.

These solutions clearly can help define the initial objectives for implementation purposes. The planning assumptions, project scope, feasibility assessment and possible barriers related to this project are discussed below.

Planning Assumptions

- Arizona Health-e Connection would have the ability to generate the required resources for this project.
- All related legislative and regulatory changes identified by the LWG would be enacted in a timely fashion.
- The data is available from several different agencies within the state.

Project Ownership and Responsibilities

It has been recommended to the Arizona Health-e Connection that this project be implemented once the non-profit is staffed and funded. The Arizona Health-e Connection Board would be responsible for supervising the work of the consultant hired to define the requirements for the provider directory.

Project Scope

The proposed project would address the following items:

- Design a centrally-managed index of all providers in Arizona:
  - Core reference file for virtually every other application in the Health-e Connection project, including Medical Trading Areas (MTAs)/RHIO
  - Consistent identification of providers
  - Consistent access controls
  - Authoritative reference source of providers

The project scope will not recommend or identify specific technology vendors or prepackaged solutions. The intent of the project is to define requirements a technology solution will have to meet and to help Arizona Health-e Connection issue an RFP for the actual provider directory.

The IPWG recognizes that the project scope can be refined by the responsible agency/entity at the time of funding and commissioning of the project to ensure that stakeholder interests and objectives are fulfilled.

Project Tasks

Based on the Arizona Health-e Connection assuming ownership of this project, the project tasks are as follows:

- ***Create core reference file for virtually every other application in the Health-e Connection project, including RHIOs:*** This would require the consultant to research data use, data needs and the development of a data dictionary, data structures and data schema as they pertain to a master provider index. The master provider index will need to be standardized for the state of Arizona for use by all Medical Trading Areas / RHIO's. The costs and benefits of different technology would need to be considered as well.

- ***Consistent identification of providers:*** Since there are several organizations in Arizona that have listing of providers, it will be necessary to review each database and determine the commonality as well as the differences in the methods used to identify the providers. A National Provider Identifier (NPI) is in development and will need to be coordinated with the state level directory once this project is funded. The consultant will need to research the scope of this particular task and determine the best approach to reconciling the identifiers for the state level directory.

- ***Consistent access controls:*** Access control should be role-based. It is expected that the Authentication, Authorization, Access and Audit project will recommend best practices for defining role-based access controls within the provider directory. The consultant will need to work closely with this project to ensure the needs are met for the provider directory access control.

- ***Authoritative reference source of providers:*** This portion of the project would involve developing a method to identify legitimate providers and their permission levels. The consultant will need to work closely with the NPI group to ensure that Arizona is using the same types of methods to identify legitimate providers.

Project Timeline and Milestones

The project timeline and milestones for retaining the consultant and moving forward with this project are as follows:

- Finalize list of consultants February, 2007
- Statement of work to consultants by end February, 2007
- Quotes due end March, 2007
- HIE Team at Arizona Health-e Connection recommend consultant from those providing quotes/bids
- Approval of consultant from 501(c)(3) governance board April 2007
- Requirements developed by consultant June, 2007

An assumption has been made the Arizona Health-e Connection (new non-profit entity) will take responsibility for this project. The project will be presented at the initial board meeting of Arizona Health-e Connection in late February.

Projected Cost and Resources Required

As bids are solicited for developing the requirements to implement the provider index, the cost of this project will become clear. Initially, one or two consultants will be retained to define the requirements for the provider index and the security issues surrounding it.

Means for Tracking, Measuring and Reporting Progress

The Arizona Health-e Connection Board will track progress in interviewing and retaining the consultant. The results will be measured based on the dates noted above under "Project Timeline".

Impact Assessment on all Stakeholders

A master provider directory is an essential step in creating a secure and private e-health data exchange system, as it is a mechanism for authenticating providers to control access. Of course, the challenge will be making sure any information that is updated and accurate.

Feasibility Assessment

It is feasible that this project will begin once the Arizona Health-e Connection is staffed and funded. Using the procurement process outlined below, this project has a high potential of being implemented.

- Consultant selection through an informal procurement process:
    - Identify a list of potential consultants
    - Provide a high-level statement of work to potential consultants
    - Request an estimate on time and cost
    - Request proposed approach

Potential Barriers

Since the Executive Leadership Team of the Arizona Health e Roadmap has already reviewed this project and understands the importance of a Master Provider Index, the only barriers we may face are as follows:

- Funding availability
- Identifying the appropriate consultant(s)
- Inadequate buy in by the medical community

II. Research on specific technology and process solutions for Authentication, Authorization, Access and Audit.

The IPWG group combined several different solutions identified in the interim analysis of solutions report under this project. Examples of solutions that were considered relevant here include:

- Participating entities will be authorized to access health information handled by the exchange. Models for such an exchange include the Centralized, Federated and the Hybrid types.
- Clearing house agency to authenticate participants in a health information exchange network.
- Develop clear role-based authorization standards for all entities in the network.
- Centralized provider directory within the state
- Biometrics for authentication of individuals involved in health information exchange
- Explore the viability of authentication tools currently available, such as swipe access to hospitals. Information can be tracked on the card itself.
- Unique Patient Identifier– Options are to use a number generated for each individual (such as a National Provider ID) or to use algorithms to uniquely identify individuals in the health information exchange.
- Implement a personalized health smart card.

These solutions clearly can help define the initial objectives for implementation purposes. The planning assumptions, project scope, project tasks, project timeline and milestones, feasibility assessment, and possible barriers related to this project are discussed below.

Planning Assumptions

- Arizona Health-e Connection and the Regional Health Information Organizations (RHIOs) have the ability to generate the required resources for this project.
- All related legislative and regulatory changes identified by the LWG would be enacted in a timely fashion.
- The RHIOs and Arizona Health-e Connection establish a business relationship to facilitate health information exchange.

Project Scope

The proposed project would address both process and technology oriented issues related to authentication, authorization, access and audit. The project scope, however, will not recommend or identify specific technology vendors or pre-packaged solutions. The intent will be to define process and technology standards that can be validated and verified by the participating entities. These process and technology standards could be considered minimum set of requirements for participation in the health information exchange.

The IPWG recognizes that the project scope can be refined by the responsible agency/entity at the time of funding and commissioning of the project to ensure that stakeholder interests and objectives are fulfilled.

Project Tasks

Given that the project ownership and responsibilities cannot be clearly identified at this time and that funding sources for the project are yet unclear, this interim report discusses the project tasks at a high level. The IPWG expects the project tasks to be more clearly laid out when the project is funded and initiated.

Authentication: Authentication standards for the exchange should consider the costs and benefits of approaches to authentication. The driving principle should be to cost-efficiently maximize protection of patient information. One of the project outcomes should be the identification of the minimum requirement for authentication. For instance, single-factor authentication (for example, a user ID and password) could be defined as the minimum standard for participation in the exchange. More stringent methods such as two-factor authentication (for example, user ID-password and smart card) and three-factor authentication (for example, user ID-password, smart card, and a bio-metric ID) should be evaluated for their cost effectiveness with the help of the stakeholder organizations involved in the exchange.

Authorization: Procedures and processes for authorization of individuals in the exchange should be clearly defined. For example, participating entities might agree to take responsibility for authorizing a provider's access to patient information, maintaining the provider's account and terminating the provider's account when he/she is no longer part of the organization.

Access: Access control should be role-based. It is expected that the project will recommend best practices for defining role-based access controls within the participating organizations and the exchange. The recommendations will be tailored to address the specificities of the participating entities such as their financial ability, process capabilities and size.

Audit: Minimum requirements for audit tracking will be defined and in conformance with HIPAA and state laws.

In addition to these requirements, it is expected that the project will clarify requirements for business continuity, public health responsibilities, information breach, information loss, and other such incidents that threaten security and integrity of patient health information.

Project Timeline and Milestones

While at this time it is too early to identify the milestones for this project, it is expected that basic standards for authentication, authorization, access, and audit will be defined within the first few months of commissioning this project. These standards will have to be continuously monitored and modified based on stakeholder feedback. It is recommended that a task force be formed by the project owner for this purpose. Membership for task force can be drawn from member organizations.

Feasibility Assessment

This proposed project is considered feasible if the resources required are available. Technical feasibility assessment will include the evaluation of existing and emerging technology and process solutions in the domain of health information exchange and/or other industry sectors that have successfully implemented their own electronic information exchange (e.g., banking, travel, etc.). Financial feasibility assessment will conduct the cost estimation of implementing the selected technology and process solutions (HIT) for HIE. Finally, managerial feasibility assessment will refer to the study of organizational cultures and changes necessary to introducing the HIT for authentication, authorization, access, and audit.

Possible Barriers

- Funding unavailability
- Rapid changes in security technologies
- Outdated infrastructure
- Cultural resistance to changes incurred by the proposed solutions

- Lack of required standards
- Hesitance to adopt existing standards
- Difficulty of integration with existing solutions
- Lack of public awareness
- Inadequate consumer buy-in

III. Create a state repository for disseminating best practices and technology solutions as they relate to security and privacy.

While the other implementation plans identified in this report are derived out of the solutions generated by the SWG, the IPWG the group recognized that there was no best practices repository regarding health information security and privacy. The group felt that a repository could provide a guide to identify appropriate implementation plans for the state. As a result, the consensus of the IPWG was to create a project around developing a best practices repository for Arizona. The IPWG identified the need for this project given the fact that various stakeholder organizations as well as other initiatives within the state have already committed time and resources to designing and implementing solutions that impact the security and privacy of health information. While a variety of solutions have been adopted by organizations across the state, there is currently no clearly identified source of information regarding the successes that organizations have had with their individual approaches. The IPWG suggested the need for one state repository that would contain best practices and technology solutions that have been implemented by individual organizations, so that state-wide initiatives such as those potentially taken by Arizona Health-e Connection would have the advantage of consolidating existing practices and identifying those most appropriate for future implementation.

Planning Assumptions

- Arizona Health-e Connection will have the ability to generate required resources for this project.
- Various stakeholder organizations and Arizona Health-e Connection will establish business relationships to facilitate the creation and sustenance of the state repository. These business relationships will determine how much information each organization will contribute to the repository along with rules about who will own the data and how often the best practices repository will be updated with new information.
- All related legislative and regulatory changes identified by the LWG will be enacted in a timely fashion.

Project Ownership and Responsibilities

Since the proposed project involves a state-wide effort, it has been recommended that Arizona Health-e Connection be responsible for its implementation. Once the non-profit organization is staffed and funded, it is expected that resources will be dedicated to develop necessary business relationships with all the entities that could potentially contribute information to the repository. The entity would also be responsible for providing oversight once the project has been commissioned to the appointed project management team.

Project Scope

The proposed project would address both the technology issues related to the design and development of the repository as well as the information types and sources of this information that will be maintained in the repository. The project scope, however, will not recommend or identify specific technology vendors or pre-packaged solutions. The project scope can be further refined as the state non-profit agency assumes responsibility for commissioning and funding this project.

Project tasks

- Define the technology infrastructure for the repository
- Define location and ownership of the repository
- Define the type of content that will be stored and the necessary formats
- Define contributors and develop business relationships with them
- Define roles related to the design, development and maintenance of the system

Project Timelines and Milestones

While it is too early to establish timelines for this project, it is expected that the project milestones would include the following:

- Refine the scope of the project and develop a plan
- Define high level requirements for the repository
- Develop an RFP
- Obtain estimates and establish timelines
- Define detailed design

Since the proposed project is at a very early conceptual stage at this time, the expectation is that more details regarding the project will emerge once the project is adopted by Arizona Health-e Connection. Arizona Health-e Connection, if it commissions the project as recommended by the IPWG, will be able to generate more information on the projected costs and resources required, means for tracking, measuring and reporting progress, and the impact assessment on all stakeholders.

Feasibility Assessment

The proposed project is considered feasible because Arizona health care providers often work collaboratively to develop common practices for health information management. For example, many of the state's hospitals adopted the Arizona HIPAA Privacy Tool Kit, which established many common practices across the hospital community. While these procedures do not address security procedures, the hospital and broader provider community likely will collaborate to develop these. Moreover, the technology to build and maintain such repositories is well established. Implementing this project would require Arizona Health-e Connection to adopt this project and give it priority over competing projects considering the value it would add to the state of Arizona in improving its healthcare capabilities. Arizona Health-e Connection would need to provide funding and other resources for this project and have confidence in the team selected to design and implement the project.

Possible Barriers

To achieve a successful implementation of this project, the following barriers would have to be overcome:

- Arizona Health-e Connection may not have funds available for this project
- Stakeholder organizations do not participate in developing the best practices for security and privacy of health information
- Ineffective management of repository by subject matter experts

IV. Education and outreach program

The IPWG group unanimously agreed that educating stakeholders and consumers about the process and outcomes of this project will be extremely important to the success of any initiatives that Arizona will take in the HIT/HIE arena. Education and outreach programs will

focus on informing the public as well as key stakeholders about the recommendations proposed in this report as well as other initiatives that are underway in the state. Recognizing the importance of an education program, Arizona is already taking concrete steps towards putting together a one-day event that is expected to be the first step of a comprehensive education and outreach strategy. The Education Working Group (EWG) is taking the lead in planning and conducting the session. The one day event is scheduled for March 20th, 2007 and the section below details the plans for this session.

Planning Assumptions

- Sponsorship for this event will easily available
- The state's leadership in the HIT/HIE area will participate in the event
- More than 300 participants will attend the event

Project Scope

The proposed program has the primary objective of educating participants about Arizona specific initiatives and programs related to HIT and HIE. An hour and a half of time during the day will be dedicated to the AHPP project. During this time, the EWG and the project management team specifically want to educate participants about two critical topics: (a) the stages and processes used during this project to achieve outcomes, (b) the interim implementation plan.

Project Tasks

- Identify the objectives and scope of this session
- Identify hosts for the event and establish funding
- Find sponsors for the event
- Identify potential speakers
- Create marketing plans that will reach as many stakeholders and consumers as possible
- Create web site for advertising the event and registrations
- Create operational plans for managing logistics around the event

Project Timeline and Milestones

Since the one-day event is scheduled for March 20th, it is expected that all key project tasks will be completed by the scheduled date. The project management team and the EWG are currently working on the completing projects tasks as defined above.

Projected Costs and Resources

The project management team and the EWG are in the process of determining the costs associated with the event and identifying a host and sponsors for the same.

While this one-day event is expected to be the first step in the education process, the IPWG has recommended a two-pronged strategy to be adopted for a more long-term education and outreach program. The first aspect of this strategy would be a high-level education of the public through mass media communications. The second aspect would be to target specific segments of stakeholders (e.g. physicians) and provide more comprehensive training programs that will address aspects of security and privacy issues in HIT/HIE that are specifically applicable to them. It is expected that the state non-profit e-health entity will assume responsibility for this long-term education and outreach program.

V. Form a group to investigate state specific data element standards issues and oversee implementation of national level standards for medical records.

The IPWG combined a few different solutions identified in the interim analysis of solutions report under this project. Examples of solutions that were considered relevant include:

- Developing a regional health information exchange
- Solutions for authorization and authentication problems

In the State of Arizona there is an initiative as part of the Health-e Roadmap to develop an "EMR lite" solution for the sharing of health records. Part of this initiative is to recommend HIT standards in conjunction with HIT implementation. As part of the AHPP, we will be recommending an implementation plan to address the security and privacy issues that impact the development of data element standards.

Planning Assumptions

- Arizona Health-e Connection would have the ability to generate required resources for this project
- Various stakeholder organizations will help Arizona Health-e Connection establish standards
- All related legislative and regulatory changed identified by the LWG will be enacted
- Arizona will have representation on federal standards committee to harmonize the state standards efforts

Project Ownership and Responsibilities

It is assumed Arizona Health-e Connection would be responsible for implementing this solution once they are staffed. The Arizona Health-e Connection Board would supervise the implementation. It is also assumed that Arizona would have a representative Arizona Health-e Connection who would participate in national standards development committees.

Project Scope

The scope of this project would address standardization of data elements needed to develop an EMR lite, focusing on the security and privacy issues. The project scope will not recommend or identify specific technology vendors or prepackaged solutions. The intent of this project is to determine an interest and/or need for EMR lite and analyse the security and privacy issues that may impact the development of standards for EMR lite.

The IPWG recognizes that the project scope can be refined by the responsible entity at the time of funding and commissioning of the project to ensure that stakeholder interests and objectives are filled.

Project Tasks

- Define EMR lite
- Identify and define data reporting elements that providers will be required to submit to federal and state governmental entities
- Identify relevant laws that impact standards, including standards for administrative data
- Identify the gaps in existing standards being developed at a national level
- Identify security and privacy issues as they apply to standards development, using the work from the authentication, authorization, access and audit project that is defined in this report
- Participate at a national level on standards development committees

Project Timeline and Milestones

The project timeline and milestones for this project is based on the assumption that the Arizona Health-e Connection Board will be responsible for this project. While the EMR lite committee has produced the following schedule, some items are dependant on others and the dates of completion have not yet been determined:

Define EMR lite – (ongoing through 4/30/2010)

- Identify and define data reporting elements that providers will be required to submit to federal and state governmental entities, February 28, 2007
- Identify relevant laws, February 28, 2007
- Standards for administrative data,
- Identify the gaps in the existing standards community
- Identify security and privacy issues as they apply to standards development, using the work from the authentication, authorization, access and audit project that is defined in this report
- Participate at a national level on standards development committees

Projected Cost and Resources Required

Since this project is still in the early planning phases, resources and cost have not been allocated.

Means for Tracking, Measuring and Reporting Progress

Assuming that Arizona Health-e Connection takes responsibility for this project, standard project management tools would be used to track and measure the project. A project report would be presented to the governing board.

Impact Assessment on all Stakeholders

The stakeholders impacted by this project would be the consumers, providers and payers that would benefit from the development of standards and resulting encouragement of EHR.

Feasibility Assessment

This proposed project is feasible if the resources and funding can be acquired to do the implementation. Since the planning has already started for EMR lite solutions it is entirely feasible that a project team will be formed to carry out the implementation and review the security and privacy issues around the EMR lite.

Possible Barriers

- Funding availability
- Resource availability
- Cultural resistance to changes incurred by the proposed solution
- Lack of technology in rural communities, tribal nations and smaller physicians offices
- Lack of public awareness
- Inadequate consumer buy-in
- The lack of consistency in implementing standards in existing HIT
- The ability or inability of other states being able to access information
- The ability or inability to develop something that is both flexible and scalable
- Enforcement of the governing rules of the HIE

VI. Plans for amendment of Arizona statutes and regulations.

The Legal Working Group has been analyzing legal solutions to observed barriers to e-health data exchange. Of course, the legal issues are greatly influenced by how an e-health data exchange is structured, what type of information is included, who has access to it, and for what purpose that data is provided. Because Health-e Connection has not yet planned the statewide e-health data exchange, the Legal Working Group decided that, in order to have a more concrete project in which to evaluate whether any change in state laws or regulations would be required, we would focus on the patient health summary concept being advanced by the Southern Arizona Health Information Exchange (SAHIE). As the Health-e Connection project unfolds, Health-e Connection could pursue a different model for the state-wide patient health summary or could adopt a different method of e-health data exchange entirely; however, we think it is likely that Health-e Connection or other regions across the state will adopt a patient health summary approach similar to SAHIE.

For purposes of our analysis, we will assume that the following data will be included in the patient health summary: clinical patient demographics; eligibility data; allergy list; prescription list; laboratory and radiology (text and image) results; and immunization information. The other decision relevant to analyzing potential legal barriers to implementation of a patient health summary is to whom access is granted. This might include emergency department access only; access to all providers, authenticated through a secure Web portal; access by public health officials; access by researchers (after appropriate approval by an institutional review board); access by health plans; and access by patients and their health care decision makers. In each of the sections below, we analyze potential legal barriers posed for each category potential given access to the patient health summary.

See discussion below regarding potential statutory and regulatory changes that may be proposed. With the involvement of all stakeholder communities, these proposals may change,

Planning Assumptions

- Arizona Health-e Connection Board will support the proposed statutory and regulatory amendments.
- Arizona Health-e Connection will be able to assemble significant stakeholders to develop the proposed amendments.
- Arizona Health-e Connection will locate an Arizona legislator to sponsor proposed statutory changes.
- Affected state agencies will agree to amend their regulations as proposed to remove potential barriers to e-health data exchange.

Project Ownership and Responsibilities

Arizona Health-e Connection will be responsible for proposing statutory and regulatory amendments as proposed and for locating government relations expertise to ensure success of this project.

Project Scope

This proposed project involves the evaluation of potential statutory and regulatory changes to avoid identified barriers to e-health data exchange in Arizona. Subgroups involved in evaluating these potential amendments will identify the appropriate stakeholders across Arizona to be involved in the discussion—including consumers—and will then collaboratively develop proposed statutory and regulatory amendments. With assistance from government relations personnel, Arizona Health-e Connection will pursue such change.

Project Tasks

- Complete identification of potential statutory and regulatory amendments to avoid potential barriers to e-health data exchange (by end of February 2007)
- Identify appropriate stakeholders across Arizona to be involved in the development of actual statutory and regulatory amendments and develop same (March and April 2007)
- With assistance of government relations personnel, find legislator willing to sponsor bill to enact proposed statutory changes (Summer 2007)
- Interact with appropriate agency personnel regarding proposed regulatory amendments (Summer 2007)

Feasibility Assessment

We believe this project is feasible. With well-considered proposals, the involvement of a wide range of stakeholders in the legislative and regulatory process, and the support of Arizona Health-e Connection, legislative and regulatory changes are likely to be supported.

Possible Barriers

To achieve a successful implementation of this project, the following barriers would have to be overcome:

- Many of the statutory changes we will recommend deal with types of health information with special protection, such as genetic testing information, communicable disease information and mental health information. If community advocates with concerns in these areas are not included in the development of actual legislative and regulatory proposals, we could encounter their opposition in this project. We thus will make every effort to involve community advocates at an earlier stage in the project.
- Arizona Health-e Connection may not have the funds necessary to continue the legal work necessary to complete this project.

Statutory and Regulatory Amendments That May Be Proposed, after Involvement of All Stakeholder Communities, Including Consumers.

The following discussion explains the health information statutes and regulations at issues, and highlights potential problems and ideas of resolving these barriers. We emphasize that these are preliminary proposals and will be subject to discussion and evaluation by a wide range of stakeholders:

(1) Genetic Testing Information: A.R.S. § 12-2801, *et seq.* and A.R.S. § 20-448.02, *et seq.*

Background:
Arizona law contains significant restrictions on disclosure of genetic testing and information derived from genetic testing, due to the heightened concern with the potential for discrimination in employment and insurance if information related to genetic predisposition to disease is released. On the other hand, genetic testing information is becoming increasingly significant information for diagnosis and effective treatment as the industry develops “personalized medicine”; information about the genetics of a particular cancer tumor, for example, may make a significant difference in what treatment is provided to a particular patient. So, Arizona may want to re-examine whether the genetic testing statute creates a barrier to the effective disclosure of genetic testing information for these legitimate treatment purposes.

The other thing complicating an easy solution, is that the Legal Working Group learned in our inquiries that genetic testing results sometimes are not separated from "regular" laboratory results in the facility doing the testing. Moreover, both genetic testing and "regular" laboratory results are often stored together in the medical record. Thus, it may be difficult in an electronic health record system to block genetic testing results from being included in the main record, and therefore from being included in a patient health summary. If the patient health summary includes laboratory results, then, the Legal Working Group/ Implementation Working Group should consider the impact of the genetic testing information statutes on implementing a patient health summary and suggest potential statutory amendments.

Moreover, the Legal Working Group is looking ahead to full interoperable exchange of electronic health record in the future. If genetic testing and "regular" laboratory results are included in an electronic health record, the statute should not function as a barrier to exchange of electronic health records.

The Statutory Restrictions:
A.R.S. § 12-2801, *et seq.,* protects "genetic testing and information derived from genetic testing." Genetic testing includes "a test of a person's genes, genetic sequence, gene products or chromosomes for abnormalities or deficiencies, including carrier status, that: (i) Are linked to physical or mental disorders or impairments; (ii) Indicate a susceptibility to any illness, disease, impairment or other disorder, whether physical or mental; or (iii) Demonstrate genetic or chromosomal damage due to any environmental factor."[2] The phrase "information derived from genetic testing" is not defined, although an individual involved in drafting the statute has explained that this phrase was intended to cover genetic testing results and reports of those results; "information derived from genetic testing" is not intended to cover diagnosis of a disease or treatment for a disease.

A.R.S. § 12-2802(A) permits disclosure without authorization only to the patient and the patient's health care decision maker, the patient's health care provider, researchers (if federal confidentiality requirements are followed), organ procurement agencies and the state registries, and permits limited internal uses by the provider.[3] In addition, the statute

[2] *Id.* Genetic testing does not include: "(i) Chemical, blood and urine analyses that are widely accepted and used in clinical practice and that are not used to determine genetic traits; (ii) Tests used in a criminal investigation or prosecution or as a result of a criminal conviction; (iii) Tests for the presence of the human immunodeficiency virus; (iv) Tests to determine paternity conducted pursuant to title 25, chapter 6, article 1; or (v) Tests given for use in biomedical research that is conducted to generate scientific knowledge about genes or to learn about the genetic basis of disease or for developing pharmaceutical and other treatment of disease." A.R.S. § 12-2801.

[3] A.R.S. § 12-2802 permits disclosure to:
(1) The person tested.
(2) Any person who is specifically authorized in writing by the person tested or by that person's health care decision maker to receive this information.
(3) The health care decision maker of the person tested.
(4) A researcher for medical research or public health purposes only if the research is conducted pursuant to applicable federal or state laws and regulations governing clinical and biological research or if the identity of the individual providing the sample is not disclosed to the person collecting and conducting the research.
(5) A third person if approved by a human subjects review committee or a human ethics committee, with respect to persons who are subject to an Arizona cancer registry.
(6) An authorized agent or employee of a health care provider if all of the following are true:
    (a) The health care provider performs the test or is authorized to obtain the test results by the person tested for the purposes of genetic counseling or treatment.
    (b) The agent or employee provides patient care, treatment or counseling.
    (c) The agent or employee needs to know the information in order to conduct the test or provide patient care, treatment or counseling.

prohibits a person holding genetic testing and information derived from genetic testing from producing that information pursuant to a subpoena in a manner that allows identification of the person tested, unless the disclosure otherwise falls within the eleven permitted uses and disclosures listed in the statute.[4]

Importantly, the statute applies to any person who receives genetic testing information: "[A] person to whom test results have been disclosed pursuant to this article, other than the person tested, shall not disclose the test results to any other person." A.R.S. § 12-2802(F). This "pass-through" applicability applies only to test results and not to "information derived from genetic testing."

Health care organizations that are subject to regulation by the Arizona Department of Insurance also must comply with A.R.S. § 20-448.02. This statute requires an insurance company to obtain written informed consent for genetic testing, and prohibits release of the genetic testing results to *anyone* without the express consent of the person tested.[5] (A.R.S. § 12-2802 provides that it does not affect the title 20 provisions governing insurance entities' handling of genetic testing information.)

Potential Legal Barriers and Proposed Solutions:
In our evaluation of the genetic testing information confidentiality statutes' impact on e-health data exchange, the Legal Working Group noted the following potential legal barriers to implementing a patient health summary or interoperable electronic health records:

(a) The phrase "information derived from genetic testing" in A.R.S. § 12-2801 is not defined, although an individual involved in drafting the statute has explained that this phrase was intended to cover genetic testing results and reports of those results; "information derived from genetic testing" was not intended to cover diagnosis of a disease or treatment for a disease. We may thus want to consider an explicit amendment to the statute that excludes diagnosis of a disease or treatment for a disease from the definition.

(b) A.R.S. § 12-2802(F) applies to any person who receives genetic testing, and provides that "a person to whom test results have been disclosed pursuant to this article, other than the person tested, shall not disclose the test results to any other

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(7) A health care provider that procures, processes, distributes or uses:
  (a) A human body part from a deceased person with respect to medical information regarding that person.
  (b) Semen or ova for the purpose of artificial insemination.
(8) A health care provider to conduct utilization review, peer review and quality assurance pursuant to section 36-441, 36-445, 36-2402 or 36-2917.
(9) The authorized agent of a federal, state or county health department to conduct activities specifically authorized pursuant to the laws of this state for the birth defects registry, children's rehabilitative services, newborn screening and sickle cell diagnosis and treatment programs and chronic, environmentally provoked and infectious disease programs.
(10) To obtain legal advice, the legal representative of a health care provider that is in possession of the medical record.
(11) A health care provider that assumes the responsibility to provide care for, or consultation to, the patient from another health care provider that had access to the patient's genetic records.

[4] A.R.S. § 12-2802(B) – (C).

[5] A genetic test in the insurance statute is similarly defined as "an analysis of an individual's DNA, gene products or chromosomes that indicates a propensity for or susceptibility to illness, disease, impairment or other disorders, whether physical or mental, or that demonstrates genetic or chromosomal damage due to environmental factors, or carrier status for disease or disorder." A.R.S. § 20-448.02.

person." This phrase would prevent providers who receive genetic testing information from releasing it for the patient health summary or even to other providers for treatment purposes. It also would prevent a third party administering the patient health summary from including this information in the summary. There are at least two options for the Legal Working Group/Implementation Working Group to consider: First, we could recommend deleting this provision entirely. Second, we could recommend restricting future disclosures by recipients to those disclosures otherwise permitted by the statute.

(c) Similarly, A.R.S. § 20-448.02 prohibits insurance companies and others subject to AZDOI jurisdiction from releasing genetic testing results to *anyone* without the express consent of the person tested. The Legal Working Group/Implementation Working Group should consider whether this restriction on insurance companies would impact the implementation of a patient health summary; for example, is it possible that information from insurance companies will be used to populate the patient health summary? If so, we could recommend amending this statutory to permit disclosures as permitted by A.R.S. § 12-2801, *et seq.*

(d) Should the genetic testing statute be clarified regarding what disclosures are permissible to providers? A.R.S. § 12-2802(A)(6) permits disclosure to "[a]n authorized agent or employee of a health care provider if all of the following are true: (a) The health care provider performs the test or is authorized to obtain the test results by the person tested for the purposes of genetic counseling or treatment; (b) The agent or employee provides patient care, treatment or counseling; (c) The agent or employee needs to know the information in order to conduct the test or provide patient care, treatment or counseling. A.R.S. § 12-2802(A)(11), on the other hand, permits disclosure to a "health care provider that assumes the responsibility to provide care for, or consultation to, the patient from another health care provider that had access to the patient's genetic records." The Legal Working Group/Implementation Working Group could clarifying when providers may obtain this information.

(e) A.R.S. § 12-2802 permits disclosure to "[t]he authorized agent of a federal, state or county health department to conduct activities specifically authorized pursuant to the laws of this state for the birth defects registry, children's rehabilitative services, newborn screening and sickle cell diagnosis and treatment programs and chronic, environmentally provoked and infectious disease programs." Is this phrase broader enough to permit public heath official access to information in the patient health summary?

(f) A.R.S. § 12-2802 does not permit payor access to genetic testing information without authorization by the patient. That prohibition would be a barrier to payors having access to the patient health summary, if that is proposed. Is this a concern? Or is payor access to genetic testing information such a concern to consumers that consumer authorization should be obtained before permitting this access?

(2) Communicable Disease Information: A.R.S. § 36-661 *et seq.,* A.R.S. § 20-448.01 and A.A.C. R20-6-1204

The Statutory and Regulatory Restrictions:
Arizona law requires certain health care providers and administrators of health care entities to report to the local health agency and others when they identify a case or suspected case of certain communicable diseases. In the case of HIV, AIDS, and tuberculosis, the specific reporting requirements are identified in statute.[6] In addition to these specific statutory requirements, ADHS regulations identify additional reportable communicable diseases.[7]

Healthcare providers must preserve the confidentiality of reportable communicable disease information and may release it only for the purposes expressly listed in the statute.[8] Communicable disease information is broadly defined information and goes far beyond HIV

[6] A.R.S. § 36-621 (HIV/AIDS), A.R.S. § 36-723(D) (tuberculosis).

[7] A.A.C. R9-6-101 *et seq.*

[8] A.R.S. § 36-664. Disclosures of communicable disease information are permitted to:

(1) The patient (called the "protected person" in the statute) or, if the protected person lacks capacity to consent, the protected person's health care decision maker;
(2) ADHS or a local health department for purposes of notifying a good Samaritan who submits a request to the department or the local health department;
(3) An agent or employee of a health facility or health care provider to provide health services to the protected person or the protected person's child or for billing or reimbursement for health services;
(4) A health facility or health care provider, in relation to the procurement, processing, distributing or use of a human body or a human body part, including organs, tissues, eyes, bones, arteries, blood, semen, milk or other body fluids, for use in medical education, research or therapy or for transplantation to another person;
(5) A health facility or health care provider, or an organization, committee or individual designated by the health facility or health care provider, that is engaged in the review of professional practices, including the review of the quality, utilization or necessity of medical care, or an accreditation or oversight review organization responsible for the review of professional practices at a health facility or by a health care provider;
(6) A private entity that accredits the health facility or health care provider and with whom the health facility or health care provider has an agreement requiring the agency to protect the confidentiality of patient information;
(7) A federal, state, county or local health officer if disclosure is mandated by federal or state law;
(8) A federal, state or local government agency authorized by law to receive the information. The agency is authorized to redisclose the information only pursuant to this article or as otherwise permitted by law;
(9) An authorized employee or agent of a federal, state or local government agency that supervises or monitors the health care provider or health facility or administers the program under which the health service is provided. An authorized employee or agent includes only an employee or agent who, in the ordinary course of business of the government agency, has access to records relating to the care or treatment of the protected person;
(10) A person, health care provider or health facility to which disclosure is ordered by a court or administrative body. This order must follow the provisions of A.R.S. § 36-665;
(11) The industrial commission or parties to an industrial commission claim (worker's compensation claim). This must follow the provisions of A.R.S. § 23-908 D and § 23-1043.02;
(12) Insurance entities pursuant to section 20-448.01 and third party payors or the payors' contractors;
(13) Any person or entity as authorized by the patient or the patient's health care decision maker;
(14) A person or entity as required by federal law;
(15) The legal representative of the entity holding the information in order to secure legal advice;
(16) A person or entity for research only if the research is conducted pursuant to applicable federal or state laws and regulations governing research;
(17) The Department of Economic Security in conjunction with the placement of children in foster care or for adoption or court-ordered placement.

and AIDS information; "communicable disease information" includes information about any "contagious, epidemic or infectious disease required to be reported to the local board of health" or ADHS that is in the possession of someone who provides health services or who obtains the information pursuant to a release (same as a "consent" or "authorization") signed by the patient.[9] At present, reportable communicable diseases include a wide variety of ailments, including flu, measles, mumps and other conditions that do not carry a stigmatizing effect.[10] Separate provisions govern when a state, county or local health department or officer may disclose communicable disease related information.[11] Given the broad scope of "communicable disease information," a patient health summary most definitely will include communicable disease information.

Significantly, if a disclosure of communicable disease information is made for a purpose for which an authorization is required, the disclosure must be accompanied by a statement "in writing that warns that the information is from confidential records protected by state law and that prohibits further disclosure of the information without the specific written authorization of the person to whom it pertains or as otherwise permitted by law."[12] Where the information is disclosed to a person pursuant to a patient's authorization, the person receiving the information also must comply with the statute.[13] (A provider is not required to include this information with a claim to a payor, as authorization is not required for providers to release this information to obtain payment. Moreover, A.R.S. § 36-664(L) provides that this statutory section does not apply to entities subject to regulation under Title 20.)

Finally, additional restrictions in the Insurance Code apply to health plans' release of HIV/AIDS information.[14] An insurer's disclosure of HIV-related information must be

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[9] A.R.S. § 36-661(4) and (5).

[10] *See* R9-6-202 (Reporting Requirements for a Health Care Provider or an Administrator of a Health Care Institution or Correctional Facility; R9-6-203 (Reporting Requirements for an Administrator of a School, Child Care Establishment, or Shelter); R9-6-204 (Clinical Laboratory Director Reporting Requirements); R9-6-205 (Reporting Requirements for a Pharmacist or Pharmacy Administrator); R9-6-206 (Local Health Agency Responsibilities Regarding Communicable Disease Reports); R9-6-207 (Federal or Tribal Entity Reporting).

[11] A.R.S. § 36-661. These persons may disclose this information only if:
(1) Specifically authorized or required by federal or state law;
(2) Made pursuant to an authorization signed by the protected person or the protected person's health care decision maker;
(3) Made to a contact of the protected person (someone who may have contracted the disease). The disclosure shall be made without identifying the protected person;
(4) For the purposes of research as authorized by state and federal law;
(5) With authorization from the director, to the national center for health statistics of the United States public health service for the purposes of conducting a search of the national death index.

[12] A.R.S. § 36-664(H).

[13] A.R.S. § 36-664(A).

[14] A.R.S. § 20-448.01. Health plans may release HIV/AIDS information only to:
(1) The protected person or, if the protected person lacks capacity to consent, a person authorized pursuant to law to consent for the protected person;
(2) A person to whom the protected person has authorized disclosure;
(3) To a medical information exchange if authorized by the protected person, but then an insurer may report only that unspecified blood test results were abnormal and must use a general code that also covers results of tests for many diseases or conditions, such as abnormal blood counts that are not related to HIV, AIDS, AIDS related complex or similar diseases;

accompanied by a written statement that warns that the information is protected by state law that prohibits further disclosure of the information without the specific written consent of the person to whom it pertains or as otherwise permitted by law.[15] Moreover, when insurers seek authorization from individuals to release HIV/AIDS information, A.A.C. R20-6-1204 imposes particular authorization requirements and provides that the authorization is only valid for 180 days.

Potential Legal Barriers and Proposed Solutions:
The Legal Working Group/Implementation Working Group may wish to consider proposing the following statutory changes:

(a) All of the individuals and entities who may have access to a patient health summary—emergency departments, other providers, public health officials, researchers and payors—may have access to communicable disease information held by providers for the purposes listed in the statute without express patient authorization. The statutory requirements in A.R.S. § 36-664(H) to include the written warning if communicable disease information is released pursuant to an individual's authorization thus would not function as a barrier to the implementation of a patient health summary.

However, the Legal Working Group/Implementation Working Group may want to consider whether this statutory requirement for a "written" warning should be amended to reflect an electronic environment.

(b) A.R.S. § 20-448.01(F) and (G) require an insurer to include a written statement with every disclosure of HIV-related information that warns that the information is protected by state law that prohibits further disclosure of the information without the specific written consent of the person to whom it pertains or as otherwise permitted by law. The Legal Working Group/Implementation Working Group may want to consider whether this statutory requirement should be amended to more closely reflect restrictions that applicable to providers, and require a warning about re-disclosure only if the information is released for a purpose not expressly listed in the statute. This is particularly true if insurers will be providing the information that will be used to populate the patient health

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(4) A government agency specifically authorized by law to receive the information. (The government agency then is authorized to redisclose the information only pursuant to this section or as otherwise permitted by law);
(5) Where ordered by a court or administrative body pursuant to A.R.S. § 36-665;
(6) The industrial commission or parties to an industrial commission claim pursuant to the provisions of A.R.S. § 23-908(D) and A.R.S. § 23-1043.02;
(7) To the underwriting departments of the insurer and reinsurers, or to those contractually retained medical personnel, laboratories, and insurance affiliates, excluding agents and brokers, which are involved in underwriting decisions regarding the individual's application if disclosure is reasonably necessary to make the underwriting decision regarding such application;
(8) With claims personnel and attorneys reviewing claims if disclosure is reasonably necessary to process and resolve claims.

A HIPAA authorization form satisfies the release requirements of this Arizona statute, except that a general authorization for the release of medical or other information is not sufficient and the release must specifically indicates its purpose as a general authorization and an authorization for the release of confidential HIV-related information, A.R.S. § 20-448.01(E), and the release form must contain the name and address of the recipient and the authorization form may not exceed 180 days from the date of signature, R20-6-1204.

[15] A.R.S. § 20-448.01(F) and (G).

summary. Moreover, the groups should consider for a "written" statement should be amended to reflect an electronic environment.

(c) A.A.C. R20-6-1204 imposes particular authorization requirements for release of HIV/ADIS information and provides that the authorization is only valid for 180 days. With feedback from insurers, the Legal Working Group/Implementation Working Group may want to suggest regulatory amendments if the authorization requirements and the validity for such authorization would be incompatible with the patient health summary.

(3) Mental Health Information: A.R.S. § 36-501, *et seq.*

Statutory Restrictions:
The Arizona mental health statutes have special restrictions on the disclosure of mental health information.[16] These statutes have limited applicability, however, and apply only to mental health providers and health care institutions licensed as behavioral health providers, including those providing inpatient and outpatient mental health services.[17] A "mental health provider" includes physicians and other providers of mental health or behavioral health services who are involved in evaluating, caring for, treating or rehabilitating a patient.[18] Health care providers that provide mental or behavioral health services but who are not licensed as behavioral health providers, such as hospital emergency departments that provide psychiatric consultations, are not subject to Arizona mental health statutes and regulations.

Information contained in mental health records is confidential and may be released only as expressly permitted by the statute.[19] (The HIPAA Privacy Rule also contains additional

[16] A.R.S. § 36-501 *et seq*
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[17] A.R.S. § 36-501(19).

[18] A.R.S. § 36-501(27).

[19] A.R.S. § 36-509 permits the disclosures without express patient consent to:
(1) Physicians and providers of health, mental health or social and welfare services involved in caring for, treating or rehabilitating the patient;
(2) Individuals to whom the patient or the patient's health care decision maker has given authorization to have information disclosed;
(3) Persons authorized by a court order;
(4) Persons doing research only if the activity is conducted pursuant to applicable federal or state laws and regulations governing research;
(5) The state department of corrections in cases in which prisoners confined to the state prison are patients in the state hospital on authorized transfers either by voluntary admission or by order of the court;
(6) Governmental or law enforcement agencies if necessary to: (a) Secure the return of a patient who is on unauthorized absence from any agency where the patient was undergoing evaluation and treatment; (b) report a crime on the premises; or (c) avert a serious and imminent threat to an individual or the public;
(7) Persons, including family members, actively participating in the patient's care, treatment or supervision. A health care provider may only release information relating to the patient's diagnosis, prognosis, need for hospitalization, anticipated length of stay, discharge plan, medication, medication side effects and short-term and long-term treatment goals. A health care provider may make this release only after the treating professional or that person's designee interviews the patient or the patient's health care decision maker and the patient or the patient's health care decision maker does not object, unless federal or state law permits the disclosure. If the patient does not have the opportunity to object to the disclosure because of incapacity or an emergency circumstance and the patient's health care decision maker is not available to object to the release, the health care provider in the exercise of professional judgment may determine if the disclosure is in the best interests of

restrictions on the use and disclosure of "psychotherapy notes"—the mental health care professional's personal notes kept separate from the regular medical record.[20])

Potential Legal Barriers and Proposed Solutions:
The patient health summary likely will not include information that falls within the scope of the mental health statutes. Arguably, health care entities governed by A.R.S. § 36-509 will not be required to release any information as part of the patient summary as it is currently defined. The only category of information relevant to behavioral health treatment or evaluation, other than patient demographics and eligibility, which should be captured through an individual's AHCCCS health plan, is the prescription list. It is likely that prescription information will be disclosed by pharmacy benefit managers and not individual behavioral health providers.

Nonetheless, the Legal Working Group/ Implementation Working Group should consider the impact of this statute on implementing a patient health summary, including:

(a) A.R.S. § 36-509(14) permits disclosure to a "third party payor or the payor's contractor to obtain reimbursement for health care, mental health care or behavioral health care provided to the patient." In other words, monetary

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the patient and, if so, may release the information authorized pursuant to this paragraph. A decision to release or withhold information is subject to review pursuant to section 36-517.01. The health care provider must record the name of any person to whom any information is given under this paragraph;

(8) A state agency that licenses health professionals pursuant to title 32, chapter 13, 15, 17, 19.1 or 33 and that requires these records in the course of investigating complaints of professional negligence, incompetence or lack of clinical judgment;
(9) A state or federal agency that licenses health care providers;
(10) A governmental agency or a competent professional, as defined in section 36-3701, in order to comply with chapter 37 of this title;
(11) Human rights committees established pursuant to title 41, chapter 35. Any information released pursuant to this paragraph shall comply with the requirements of section 41-3804 and applicable federal law and shall be released without personally identifiable information unless the personally identifiable information is required for the official purposes of the human rights committee. Case information received by a human rights committee shall be maintained as confidential. For the purposes of this paragraph, "personally identifiable information" includes A person's name, address, date of birth, social security number, tribal enrollment number, telephone or telefacsimile number, driver license number, places of employment, school identification number and military identification number or any other distinguishing characteristic that tends to identify a particular person;
(12) A patient or the patient's health care decision maker pursuant to section 36-507;
(13) The department of public safety by the court to comply with the requirements of section 36-540, subsection N;
(14) A third party payor or the payor's contractor to obtain reimbursement for health care, mental health care or behavioral health care provided to the patient;
(15) A private entity that accredits the health care provider and with whom the health care provider has an agreement requiring the agency to protect the confidentiality of patient information.
(16) The legal representative of a health care entity in possession of the record for the purpose of securing legal advice;
(17) A person or entity as otherwise required by state or federal law;
(18) A person or entity as permitted by the federal regulations on alcohol and drug abuse treatment (42 code of federal regulations part 2);
(19) A person or entity to conduct utilization review, peer review and quality assurance pursuant to section 36-441, 36-445, 36-2402 or 36-2917;
(20) A person maintaining health statistics for public health purposes as authorized by law; or
(21) A grand jury as directed by subpoena.

[20] 45 C.F.R. § 164.501.

payment is the sole purpose for disclosure. If health plans need the information for purposes in addition to monetary payment, the Legal Working Group should consider modifying A.R.S. § 36-509(A)(14) to be consistent with the definition in HIPAAA. There, "payment" is defined more broadly to include, among other activities, appropriateness of care, utilization review and review of services to determine medical necessity. 42 CFR § 164.501.

(4) AHCCCS Member Information: A.R.S. § 36-2901 and A.A.C. R9-22-512

Statutory and Regulatory Restrictions:
Statutory and regulatory restrictions apply to disclosures by the Arizona Health Care Cost Containment System (AHCCCS) and organizations that are AHCCCS contractors, providers, and noncontracting providers.[21] The AHCCCS plan and its contractors, providers and noncontracting providers may disclose information related to AHCCCS applicants, eligible persons or members in more limited circumstances than permitted by the HIPAA Privacy Rule.[22] Significantly, the regulations require the holder of a medical record of a "former applicant, eligible person, or member" to obtain *written* consent from that person "before transmitting the medical record to a primary care provider."[23] On the other hand, "subcontractors are not required to obtain written consent from an eligible person or member before transmitting the eligible person's or member's medical record to a physician who: (1) provides a service to the eligible person or member under subcontract with the program contractor, (2) is retained by the subcontractor to provider services that are infrequently used or are of an unusual nature, and (3) provides a service under the contract."[24] The regulations also do not permit release of AHCCCS member information for research purposes.

[21] A.R.S. § 36-2901 (definitions).

[22] A.A.C. R9-22-512 permits disclosures of information concerning an "eligible person, applicant, or member" only:

(1) To the individual;
(2) With authorization of the individual (where the authorization meets certain requirements);
(3) To persons or agencies for "official purposes" related to administration of the AHCCCS program. These "official purposes" include establishing eligibility and post-eligibility treatment of income; determining the amount of medical assistance; conducting or assisting an investigation, prosecution, or civil or criminal proceeding related to the AHCCCS program; performing evaluations and analyses of AHCCCS operations; filing liens on property as applicable; filing claims on estates; filing, negotiating, and settling medical liens and claims; and providing services for eligible persons and members. "[P]roviding services for eligible persons and members" is read broadly to permit disclosure for "treatment, payment and health care operations," as defined under HIPAA, and to family members or friends involved in the treatment of the member;
(4) For "official purposes" related to administration of the AHCCCS program and only to the extent required in performance of duties, to employees of AHCCCS, the Social Security Administration, Arizona DES, ADHS, the federal DHHS, the Arizona Attorney General's Office, the Board of Supervisors, AHCCCS eligibility offices, and the County Attorney, as well as employees of contractors, program contractors, providers and subcontractors.
(5) To law enforcement for the purpose of an investigation, prosecution, or criminal or civil proceeding relating to the administration of the AHCCCS program, including where the member is suspected of AHCCCS fraud or abuse (and otherwise if the law enforcement official has statutory authority to obtain the information);
(6) To a review committee pursuant to A.R.S. § 36-2917; and
(7) To the extent required in the performance of duties to various government agencies.

[23] A.A.C. R9-22-512(G).

[24] A.A.C. R9-22-512(H).

Potential Legal Barriers and Proposed Solutions:
Because the patient health summary will certainly include information about AHCCCS members, the Legal Working Group/ Implementation Working Group should consider the impact of the statute and regulation on implementing a patient health summary, including:

(a) A.A.C. R9-22-512(3) permits disclosures of information concerning an "eligible person, applicant, or member" to persons or agencies for "official purposes" related to administration of the AHCCCS program. The "official purposes" listed include "establishing eligibility and post-eligibility treatment of income; determining the amount of medical assistance; conducting or assisting an investigation, prosecution, or civil or criminal proceeding related to the AHCCCS program; performing evaluations and analyses of AHCCCS operations; filing liens on property as applicable; filing claims on estates; filing, negotiating, and settling medical liens and claims; and providing services for eligible persons and members." While we believe that the phrase "providing services for eligible persons and members" is read broadly to permit disclosure for "treatment, payment and health care operations," as defined under HIPAA, and to family members or friends involved in the treatment of the member, the Legal Working Group/ Implementation Working Group may wish to propose clarifying that point in regulations.

(b) A.A.C. R9-22-512(4) permits release of information "official purposes" related to administration of the AHCCCS program and only to the extent required in performance of duties, to employees of AHCCCS, the Social Security Administration, Arizona DES, ADHS, the federal DHHS, the Arizona Attorney General's Office, the Board of Supervisors, AHCCCS eligibility offices, and the County Attorney, as well as employees of contractors, program contractors, providers and subcontractors. The Legal Working Group/ Implementation Working Group may wish to clarify that this language permits release of information to ADHS and county public health officials for public health purposes.

(c) A.A.C. R9-22-512 does not permit release of AHCCCS member information for research purposes. The Legal Working Group/ Implementation Working Group may wish to propose an amendment to the AHCCCS regulation permitting this release.

(d) For a broader purposes, The Legal Working Group/ Implementation Working Group may wish to clarify whether this regulation applies to health care providers and under what circumstances (or whether health care providers are subject only to medical records statutes, such as A.R.S. § 12-2291 *et seq.*

<u>(5) Adult Day Health Care Facility Records: A.A.C. R9-10-511(C)</u>

Regulatory Restrictions:
A.A.C. R9-10-511(C) requires adult day health care facilities to have medical records "recorded in ink".

Potential Legal Barriers and Proposed Solutions:
This regulation should be updated to permit electronic health records.

(6) Immunization Information:

Statutory and Regulatory Restrictions:
A.R.S. § 36-135 and A.A.C. R9-6-708 restrict the purposes for which ADHS may release immunization data. Specifically, A.R.S. § 36-135(D) permits ADHS to release identifying

information contained in immunization data "only to the child's health care professional, parent, guardian, health care service organization, the Arizona health care cost containment system and its providers as defined in title 36, chapter 29, or a school official who is authorized by law to receive and record immunization records." ADHS also "may, by rule, release immunization information to persons for a specified purpose." Id. A.A.C. R9-6-708 additionally permits ADHS to release immunization information to: (1) an authorized representative of a state or local health agency for the control, investigation, analysis, or follow-up of disease; (2) a child care administrator, to determine the immunization status of a child in the child care; (3) an authorized representative of WIC, to determine the immunization status of a child enrolled in WIC; (4) an individual or organization authorized by the Department, to conduct medical research to evaluate medical services and health related services, health quality, immunization data quality, and efficacy; or (5) an authorized representative of an out-of-state agency, including a state health department, local health agency, school, child care, health care provider, or a state agency that has legal custody of a child.

A.R.S. § 36-135(E) additionally specifies that information in the ADHS immunization data system is confidential and that "a person who is authorized to receive confidential information under subsection D shall not disclose this information to any other person." Substantial penalties are in place for violating these confidentiality provision: (1) "A health care professional who does not comply with the requirements of this section violates a law or task applicable to the practice of medicine and an act of unprofessional conduct." A.R.S. § 36-135(G); and (2) "any agency or person receiving confidential information from the system who subsequently discloses that information to any other person is guilty of a class 3 misdemeanor." A.R.S. § 36-135(H).

The statute also permits a child's parent or guardian to prevent immunization information to be withheld from release. *See* A.R.S. § 36-135(I) ("At the request of the child's parent or guardian, the department of health services shall provide a form to be signed that allows confidential immunization information to be withheld from all persons including persons authorized to receive confidential information pursuant to subsection D. If the request is delivered to the health care professional prior to the immunization, the health care professional shall not forward the information required under subsection B to the department."

Potential Legal Barriers and Proposed Solutions:
If the patient health summary will be populated with immunization data from the ADHS, rather than from health care providers or other sources, the immunization statute and regulations may pose barriers to including this information in the patient health summary. The issue remains open as to whether getting this information from the ADHS immunization registry is necessary or beneficial, rather than getting the information directly from providers. ADHS information is not complete, and does not contain historical data for children who are not born in this state unless the provider chooses to put that information in the system. In addition, the data comes from billing information, which can be affected by coding problems and date discrepancies and data from primary sources should be sought. Finally, ADHS would require explicit permission from federal agencies, Indian Health Services and other states that submit voluntarily to the ADHS system, in order to include their information to Arizona Health-e Connection.

Given these considerations, if immunization information will be obtained from ADHS, the Legal Working Group/ Implementation Working Group should consider the impact of the statute and regulation on implementing a patient health summary, including:

(a) A.R.S. § 36-135 and A.A.C. R9-6-708 together permit ADHS to release immunization data to: (1) child's health care professional and AHCCCS providers; (2) parent or guardian; (3) health care service organizations and AHCCCS; (4)

school officials; (5) an authorized representative of a state or local health agency for the control, investigation, analysis, or follow-up of disease; (6) a child care administrator, to determine the immunization status of a child in the child care; (7) an authorized representative of WIC, to determine the immunization status of a child enrolled in WIC; (8) an individual or organization authorized by the Department, to conduct medical research to evaluate medical services and health related services, health quality, immunization data quality, and efficacy; or (9) an authorized representative of an out-of-state agency, including a state health department, local health agency, school, child care, health care provider, or a state agency that has legal custody of a child. This list excludes insurers that do not fall within the definition of a "health care services organization" (an HMO). The Legal Working Group may wish to consider expanding access to all types of health plans. Health plans use this information to determine provider performance, and the state and federal privacy laws should sufficiently protect the confidentiality of the information obtained by the health plans. The definition of health care service organization should be clarified to include all health plans.

(b) The statute prohibits a person who receives immunization information from ADHS from releasing it to any other person, and provides substantial penalties for violating this provision. The Legal Working Group may wish to suggest changes to the statute to remove this "pass-through" prohibition, or may wish to propose prohibiting passing on the information to individuals or entities not otherwise permitted to receive immunization information.

(c) The regulation permits release to "an individual or organization authorized by the Department, to conduct medical research to evaluate medical services and health related services, health quality, immunization data quality, and efficacy." This poses potentially two problems with researcher access to the patient health summary if it contains immunization information provided by ADHS: (1) The regulation requires the individual or organization obtain ADHS IRB review. This will create a burden for researchers if they also are required to obtain review by their own institutional IRBs. (2) The regulation could be interpreted to not permit release for clinical research (versus health services research), and could prevent access to the patient health summary for such purposes as identification of individuals for participation in clinical trials.

The Legal Working Group has to date identified three areas in which new statutes would be helpful to encourage health care organizations to participate in e-health data exchange, including a patient health summary project.

(1) Immunity from Liability:

The Legal Working Group noted that the fear of liability for relying on information provided in the patient health summary may prevent many physicians and other health care providers from utilizing this valuable resource. For example, because the patient health summary will be utilizing information from various sources to populate the records, but because we do not have a unique national patient identifier, there is a small percentage of risk that information related to other patients will be included in a patient's record. In order to address this fear of liability, we will propose a statute that provides a measure of immunity from liability for relying on information provided in the patient health summary. This will of course be a challenging issue to tackle that will require balancing the need to encourage providers and others to participate in e-health data exchange in Arizona, yet recognize legitimate claims for negligent activity.

(2) Enforcement of Violations:

The Legal Working Group also noted that it may be important for the state to enact a statute that provides penalties for unauthorized access to the patient health summary or other e-health data exchange.

(3) Subpoenas:

The Legal Working Group will consider whether an amendment of the laws regarding subpoenas and court orders should be amended. If the e-health data exchange holds information from various participants, or has the ability to "pull" information from various participants, the state could consider a statute that direct the subpoena or court order to the source of the information, not the exchange.

V. Multi-state Implementation Plans

The IPWG has not identified any multi-state implementation plans at this time. Instead, we are concentrating our efforts on implementation plans that will support the Arizona Health-e Connection roadmap.